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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,348	04/02/2002	Peter S. Nelson	UWOTL118176	6421

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EXAMINER	
NICKOL, GARY B	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 06/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/019,348	NELSON ET AL.	
	Examiner	Art Unit	
	Gary B. Nickol Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-65 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-65 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-65 are pending.

Note: Claims 2-6 lack antecedent basis for the word "fragment". It was assumed for restriction purposes, that the products claimed in Claims 2-6 were drawn to nucleic acid sequences.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

1. Claims 1-9, drawn to the special technical feature of isolated polynucleotides and nucleic acid probes.

   (Upon election of Group 1, applicant is required to further choose a nucleic acid sequence (i.e. SEQ ID NO:1, 3, 5, 7, etc.) as each nucleic acid sequence is an independent group, not a species. Applicants are reminded that any claims not reading on the elected sequence will be withdrawn as drawn to non-elected inventions.)

2. Claim 10, drawn to the special technical feature of an isolated polypeptide comprising SEQ ID NO:2.

3. Claim 10, drawn to the special technical feature of an isolated polypeptide comprising SEQ ID NO:6.

4. Claims 11-13, 15-25, drawn to the special technical feature of a method of diagnosing or predicting the susceptibility of a prostate neoplastic condition in individuals suspected of having such condition comprising measuring the amount of RNA encoding either ARSDR1, TMPRSS2 or PART-1.

   (Upon election of Group 4, applicant is further required to elect the diagnostic gene of interest, i.e. ARSDR1, TMPRSS2 or PART-1, as each gene represents an independent group not a species.)

5. Claims 11-12, 14-15, 26-35, drawn to the special technical feature of a method of diagnosing or predicting the susceptibility of a prostate neoplastic condition in individuals suspected of having such condition comprising measuring the amount of protein selected from either ARSDR1, TMPRSS2 or PART-1.

   (Upon election of Group 5, applicant is further required to elect the diagnostic gene of interest, i.e. ARSDR1, TMPRSS2 or PART-1, as each gene represents an independent group not a species.)

6. Claims 15, 36-43, in part, drawn to a method of diagnosing or predicting the susceptibility of a prostate neoplastic condition in individuals suspected of having such condition comprising measuring the activity of a protein selected from ARSDR1, TMPRSS2 or PART-1, classified in class 435, subclass 4.

   (Upon election of Group 6, applicant is further required to elect the diagnostic gene of interest, i.e. ARSDR1, TMPRSS2 or PART-1, as each gene represents an independent group not a species.)

7. Claims 44-50, drawn to the special technical feature of a method of identifying compounds capable of inhibiting the activity of ARSDR1.

8. Claims 51-53, drawn to the special technical feature of a method of identifying compounds capable of inhibiting the activity of TMPRSS2.

9. Claims 54-55, drawn to the special technical feature of a method of treating prostate cancer comprising administering an inhibitor of ARSDR1, wherein said inhibitor is a short-chain dehydrogenase/reductase inhibitor.

10. Claims 54, 56-57, drawn to the special technical feature of a method of treating prostate cancer comprising administering an inhibitor of ARSDR1, wherein said inhibitor is an ARSDR1 antisense polynucleotide.

11. Claims 54, 58, drawn to the special technical feature of a method of treating prostate cancer comprising administering an inhibitor of TMPRSS2, wherein said inhibitor is a serine protease inhibitor.

12. Claims 54, 59-60, drawn to the special technical feature of a method of treating prostate cancer comprising administering an inhibitor of TMPRSS2, wherein said inhibitor is a TMPRSS2 antisense nucleic acid.

13. Claims 54, 61-62, drawn to the special technical feature of a method of treating prostate cancer comprising administering an inhibitor of PART-1 wherein said inhibitor is a PART-1 antisense nucleic acid.

14. Claims 63-65, drawn to the special technical feature of antibodies that selectively bind amino acids comprising SEQ ID NO:2, 4, or 6, classified in Class 530, subclass 387.1.

(Upon election of Group 14, applicant is required to further choose the corresponding amino acid sequence (i.e. SEQ ID NO:2,4,6) to which the antibody is specific for as each antibody is an independent group, not a species. Applicants are reminded that any claims not reading on the elected sequence will be withdrawn as drawn to non-elected inventions.)

The inventions listed as Groups 1-14 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking Groups 1-14 appears to be an isolated polynucleotide capable of hybridizing under stringent conditions to at least 15 contiguous nucleotides from a nucletoide sequence selected from the group consisting of SEQ ID NOs: 1, 3, 5, 7, 8, 9, 10, and 11 (Claim 1)

However, Xu *et al.* (US Patent No. 6,465,611, January 15, 1999) teach an isolated polynucleotide capable of hybridizing under stringent conditions to at least 15 contiguous nucleotides from a nucletoide sequence selected from the group consisting of SEQ ID NOs: 1 (see attached sequence comparison).

Therefore, the technical feature linking the inventions of Groups 1-14 does not constitute a *special* technical feature as defined by PCT Rule 13.2 as it does not define a contribution over the prior art.

SPECIES ELECTION:

Group 6 (Claims 38-41) is generic to a plurality of disclosed patentably distinct species drawn to different assays for product formation (i.e. measuring the appearance of reduced coenzyme, disappearance of non-reduced coenzyme, etc.).

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each species has a different special technical feature which encompasses distinct methods steps, objectives, and reagents all of which impart different biological functions and uses.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after

the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 571-272-0835. The examiner can normally be reached on M-Th, 8:30-5:30; alternate Fri., 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gary B. Nickol Ph.D.
Primary Examiner
Art Unit 1642

June 24, 2004

GARY NICKOL
PRIMARY EXAMINER